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MOORE & VAN ALLEN PLLC
P.O. BOX 13706
Research Triangle Park, NC 27709

EXAMINER	
SAYALA, CHHAYA D	

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1781	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,730	KYLE ET AL.	
	Examiner	Art Unit	
	CHHAYA SAYALA	1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *81-83,90-100,103,104 and 107-111* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *81-83,90-100, 103-104, 107-111* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 81-83, 90-100, 103-104, 107-111 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant is "making" a fish or mollusk or shrimp by feeding certain ingredients that are intended to enhance the level of DHA and certain carotenoids. The fish or mollusk or aquatic creature is defined by its feed. The feed contains as claimed:

1) hydrolyzed plant protein

2) bacteria comprising a carotenoid wherein the carotenoid is selected from lutein, zeaxanthin and lycopene, wherein the lutein, zeaxanthin or lycopene is derived from (sourced from) marigold petals, Lvcium Chinese Mill Berries, tomatoes, microalgae, diatoms, and bacteria

3) microalgae comprising DHA.

At ¶ [0033] the specification states that there are no reports (in prior art) of shrimp or salmonid fish where astaxanthin was not the predominant carotenoid. Applicant states that the inventors have surprisingly found that the carotenoid level in the aquatic animal can be modulated wherein the main carotenoid was not astaxanthin. Example 5

describes feeding "high" lutein to Striped Bass, example 6 shows "high" zeaxanthin to shrimp, example 7 shows "high" lycopene to shrimp, and example 8, "high" lutein to shrimp and example 12, "high" zeaxanthin to shrimp. Because of the state of the art, it is unclear that the mere feeding of fish according to claim 1 results invariably, in high levels of lutein, zeaxanthin or lycopene in all kinds of aquatic animals when fed for any length of time/phase. That is to say, when prior art established that astaxanthin was the predominant carotenoid in shrimp and fish, there is no evidence that high levels of the 3 carotenoids claimed were achieved in any and all aquatic animals by feeding them with the ingredients in the ranges 60 to 200 or 500 mg/kg of body weight. The examples merely show feeding but do not disclose what levels were achieved, if at all. There is no clear definition of what "high" represents. For instance, is "high" related to astaxanthin levels in the animal or to the 'normal' levels of zeaxanthin, lutein and lycopene? This is not clear. "High" is a relative term. Further, the examples teach feeding these animals the specific carotenoid only at a certain time in its feeding period, and it is not clear if the so called higher level was achieved by feeding for any length of time or only before harvest, and for only a defined period before harvesting.

With regard to the increase of DHA in all the aquatic animals that these claims cover (claim 81), the prior art and indeed, the instant specification shows that shrimp and catfish naturally have low levels of DHA and "typically have a DHA/EPA ratio of 0,8. See ¶ [0037. While the claims state that all aquatic animals had a ratio of DHA/EPA greater than 1, there is nothing in the specification to show that this was actually achieved and the naturally occurring ratio was increased. There is nothing to establish

that feeding the animal with the microalgae containing DHA in the claimed range was consistent in increasing that natural ratio referred to in the specification, a result not described or reported by prior art.

While prior art does not show an increase in DHA levels to the extent claimed, when microalgae were fed to aquatic animals, there is no corresponding teaching that a bacteria comprising carotenoids as listed, enriched the animal being fed (and claimed) in such a way as to raise its levels to any patentable significance. If applicant is extrapolating results obtained with DHA in prior art, to carotenoids, in order to establish results of patentable significance even in face of prior art showing that it was astaxanthin that was the predominant carotenoid, there is no expectation of the claimed result and no correlation between DHA and the 3 carotenoids, because there is no result showing that increasing the 3 carotenoids actually produced a patentable increase in the animal when fed as claimed in claim 1 because it was so with DHA and such fatty acid enhancement was realized in prior art. Therefore, the invention can only be practiced with undue experimentation.

Further, the specification states that at ¶ [0038] that certain supplementation *amounts* of zeaxanthin or lutein brought about such increase. However, there is no evidence that all such amounts were incorporated/assimilated in the aquatic animal to provide an animal with "higher" levels of carotenoids. There is no evidence that such assimilation and incorporation were obtained at high levels (wherein "high" is obscure in the specification) without oxidation, given that such carotenoids are highly susceptible to oxidation. Further, it is well known that salmon for example, convert zeaxanthin to

astaxanthin *quite readily and naturally in the skin.* (See Kitahara, Comparative Biochemistry and Physiology Part B: Comparative Biochemistry, Volume 78, Issue 4, 1984, Pages 859-862- -reference not provided). Given such factors in prior art and the amount of guidance and direction in the specification, the lack of working examples to reflect whether any so-called "high" amounts were actually realized in any and all aquatic creatures and in the claimed amounts covered by the claims herein, and the factors to be considered in evaluating whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" , it is being held that the invention as claimed lacks enablement and it is a conclusion reached by weighing all the below noted factual considerations. *In re Wands,* 858 F.2d at 737, 8 USPQ2d at 1404.

These factors include, but are not limited to:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations. *In re*

Wands, 858 F.2d at 737, 8 USPQ2d at 1404. In fact, the examiner has reviewed the prior art statements made by applicant and the working examples as well as the prior art that describe oxidative stability of these compounds in these animals even as they are ingested, to conclude that there is little evidence that "high" levels can be achieved by one of ordinary skill in the art in practicing the invention as described unless he is subjected to undue experimentation. In addition, applicant is claiming the addition of bacteria that comprises carotenoids **selected from** lutein, lycopene and zeaxanthin. There is no guidance as to such bacteria that can be selected based on lutein, zeaxanthin or lycopene and how such selection can be conducted. Next, applicant claims that the **bacteria comprising carotenoids that is selected from lutein, zeaxanthin or lycopene is a bacteria that is further derived from marigold petals, Lvcium Chinese Mill Berries, tomatoes, microalgae, diatoms, and bacteria**. Clearly transgenesis is intended? Yet, there is no guidance, direction or working examples in the specification, as to how such techniques are achieved.

2. Claims 81-83, 90-100, 103-104, 107-111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 81, "vegetarian" is unclear. The specification does not define this term adequately to define the metes and bounds of this term. For instance, some vegetarian diets include dairy and others include eggs. See for instance, ¶ [0035] of the

specification includes as a preferred embodiment, egg phospholipids and fish extracts in the composition, a composition called "vegetarian".

Claim 82 does not further limit claim 81 as recited. Perhaps applicant intends to further include EPA and ARA.

Claim 96 recites a total extractable fat (DHA) from the fish and it is not clear whether this refers to the fish after it is "made" by feeding and then it is extracted soon after? Is DHA the extractable fat? Extractable fat has no antecedent basis. The claim is to an animal made by feeding. That is, the animal is being produced by feeding it. A product-by-process claim is a product. By reciting an extractable fat, is applicant now describing the fish (product) or the feeding of it (process)? That is to say, what is this claim further limiting? By reciting "extractable", does applicant intend that the fish be extracted for fat? Is there another process being recited also? In claim 108, applicant claims a phospholipid added to the feed. The limitation that the phospholipid is extracted from a marine algae is confusing. Is this limitation a product-by-process within a product-by-process, or is the extraction from the microalgae of claim 81? Which microalgae in claim 81?

Claim 81 is indefinite in reciting that the carotenoid that is included within the bacteria (line 3) that is being fed to the animal is selected from lutein, zeaxanthin and lycopene. It is not clear how the bacteria (line 3) that comprises carotenoids can be further selected from marigold, microalgae, etc, and another bacteria at line 8 or perhaps the same bacteria at line 3? Is this a product-by-process within a product-by-process? Is the bacteria at line 3 that comprises the carotenoid, related to the bacteria of line 8 from

which the carotenoid is derived from? Claim 81 is a very confusing and unclear product claim. Neither the metes and bounds of this claim are properly defined nor does it make clear what exactly is being claimed, making search and examination tasks an extreme burden. Not ethat claim 81 has two microalgae and two bacteria recited.

Applicant's claims are directed to a fish "made by" feeding it with 1) **hydrolyzed plant protein** and 2) a **bacteria** that comprises a carotenoid 3) a **microalgae** that comprises DHA. Applicant's claims are to a product written in a product-by-process format. It is not clear if the limitation that "at least 1% of the fat content of the feed is DHA" is intended to include fat from other parts of the feed. Is there fat other than DHA? If so, there is no proper antecedent basis for the above limitation. **The claims are being examined as best understood and they are being interpreted as product claims written in a product-by-process format.**

In claim 81, if the carotenoid that the bacteria is comprised of, is selected from lutein, zeaxanthin and lycopene, then the limitation that "less than 50% of the total carotenoid content of the aquaculturally-raised aquatic animal is **astaxanthin"** lacks proper antecedent basis.

In claim 83, does the ratio pertain to the animal before being fed or after? Note that claim 82 from which this claim depends refers to the feed containing EPA and DHA.

The "microalgae" of claim 90 is not clear; does it refer to the microalgae in line 3 or line 8?

In claim 91, the amount of DHA referred to should be clarified as referring to the feed.

In claim 94, the amount of DHA referred to should be clarified as referring to the feed. Claims 103-104 should also be clarified as to the feed containing the lutein and zeaxanthin.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 81-83, 90-96, 99, 103-104, 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle et al. (US Patent 5397591) and Barclay (US Patent 5698244) in view of Gierhart (US Patent 5427783) and further in view of Nielson et al. (US Patent 5989600).

Kyle et al. disclose a biomass of *C. cohnii* that contains 30-40% DHA being used for aquaculture such as fish. By using the biomass aquaculturally for fish, Kyle et al. has produced an "aquaculturally-raised" fish or shrimp or oyster, as claimed, and meets claim 81. See col. 6, lines 35-38. By disclosing such a high level of DHA claims 82-83 have been met.

Barclay is drawn to, as the title suggests, raising animals having high concentrations of Omega-3 fatty acids as shown at col. 2 and col. 4, which includes the

fatty acids claimed at instant claim 82, by feeding harvested biomass from the genus Thraustochytrium (col. 3, line 14). See col. 5, line 5, lines 15, 20-24. Barclay teaches feeding the biomass to fish, shrimp, etc. (see claims). Barclay discloses that the oil content of the harvested cells is 25-50%.

Barclay discloses feeding elevated levels of DHA in the form of whole biomass paste, but Barclay does not disclose the DHA content of the feed/ animal as claimed in claims 91 and 94. Since Barclay discloses the same biomass to the same animal, including shrimp, as claimed, it must be inherent that the DHA content and the DHA to EPA ratio is the same. Alternatively, the burden to find the DHA content of the aquacultured animals (or the feed as claimed) of Barclay (col 5, lines 19-20) is being shifted to applicant because the Office does not have the resources to obtain and measure such DHA contents to the variety of animals or the DHA content of microalgae as fed and shown by Barclay and/or animals encompassed by claim 91. Similarly, as to the extractable fat of the aquacultured fish of Barclay as in claim 96, since the Office cannot obtain prior art products and measure the DHA content to be more than about 5%; such characteristics that applicant has chosen to describe his product by, cannot be determined by the Office based on its resources or the lack thereof and that burden is being shifted to applicant. Based on the extent of the Barclay disclosure however, as described herein above, this amount must be inherent. Similarly, to extract the fat of the aquacultured mollusk of Barclay as in claim 99 and the measurement of the DHA content to be more than about 10% cannot be determined by the Office based on its resources or the lack thereof and that burden is being shifted to applicant. Based on

the extent of the Barclay disclosure however, as described herein above, this amount must be inherent.

Both Barclay and Kyle do not disclose the carotenoid obtained from the bacteria, which in turn is derived from microalgae (claim 81, line 8). However, Barclay discloses that the harvested biomass feed also contains carotenoids (col. 4, lines 56-58). Therefore, Barclay discloses that the carotenoid was obtained from microalgae. The references do not teach that the bacteria comprises from carotenoid selected from lutein, zeaxanthin and lycopene. However, since the reference discloses the same microalgae, then the microalgae must contain the same carotenoids. With regard to the bacteria that comprises carotenoids, Gierhart discloses such a bacteria that contains zeaxanthin, and to incorporate such a bacteria that comprises carotenoids would have been obvious since Gierhart discloses the product is a feed additive (col. 1). As for the carotenoids that is included in the bacteria being selected from **marigold petals, Lycium Chinese Mill Berries, tomatoes, microalgae, diatoms, and bacteria** (claim 81, lines 7-8), neither any reference nor the instant specification discloses such a limitation, however, the claim is written in a product-by-process format and it is novelty of the product that needs to be established and not that of the recited process steps. See *In re Brown*, 173 USPQ 685 (CCPA 1972); *In re Wertheim*, 191 USPQ (CCPA 1976). If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). See MPEP 2113 which states that the process

steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. The specification does not establish that the product can only be defined by the process steps or that the process steps impart any distinctive characteristic.

With regard to claims 103-104 as to the amounts of lutein and zeaxanthin, although the claim recites such amounts as being part of the animal, the specification only discloses such amounts as being in the feed. In view of the fact that the references applied show the caroteinoids as feed additives, then determination of amounts would have been within the skill of the artisan according to the effects desired. The references of Barclay and Kyle do not disclose the inclusion protein hydrolysates in their feed. Nielsen teaches that protein is essential in feed compositions and use of vegetable protein is common in animal feeds. Hydrolyzing such vegetable proteins removes anti-nutritional factors and solubilizes vegetable proteins and facilitates their use in feeds including fish feeds (col. 1, line 65 and col. 2). Thus the incorporation of hydrolyzed proteins of the type shown by this reference in fish feeds would have been prima facie obvious.

Note that all 3 ingredients or elements of the feed have been established by prior art for the same purpose, feeding aquatic animals, thereby rendering their use together obvious because their usefulness has been shown by prior art individually; combining them, therefore, requires no more than routine skill. By combining them, the concept of

a vegetarian diet has been met within the meaning of the term as defined by the instant specification. It is to be noted that the feed composition being vegetarian or non-vegetarian is a personal choice and an obvious one at that, even for a fish.

4. Claims 97, 98, 100, 109-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle et al. (US Patent 5397591) and Barclay (US Patent 5698244) in view of Gierhart (US Patent 5427783) and further in view of Nielson et al. (US Patent 5989600) taken with JP 2002-253140 and JP 60110250

The primary references are taken as discussed above. Barclay discloses the "animal" as fish but does not disclose it to be a catfish, mollusk or abalone. When Barclay discloses shrimp, oyster, fish and seafood animals, it is being held that such varieties would have been obvious to one of ordinary skill in the art at the time the invention was made, barring any evidence to the contrary. Barclay does not disclose taurine, but JP 2002-253140 discloses the use of carotenoids and taurine as feed for aquaculturally raised fish (see translation "farmed fish"). It would have been obvious to include such ingredients already being used for the same purpose and determine amounts suitable for the type of animal because clearly, amounts for one type would not be suitable for another, such as catfish versus mollusk. However, note that the JP patent teaches an amount of taurine that falls within the range claimed. Since claim 81 is rendered obvious by the combination of references, then to find the suitable length of time for feeding the aquaculturally raised animal so that it can be harvested would have been obvious to the practitioner.

5. Claims 107-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle et al. (US Patent 5397591) and Barclay (US Patent 5698244) in view of Gierhart (US Patent 5427783) and further in view of Handelman (US Patent 6075058) or JP 06070698.

The primary references are taken as discussed above. They do not show that the bioavailability of the carotenoids would be enhanced by using them with phospholipids, well known for its property of being an emulsifier. The secondary references disclose the enhanced bioavailability of carotenoids by combining them with phospholipids. For this advantage it would have been obvious to combine carotenoids in the feed composition with phospholipids. With regard to claim 108, applicant claims obtaining the phospholipid from marine algae. Claim 81 is a product claim, written in a product-by-process format. Claim 108 depends from claim 81 and is another product (phospholipid)-by-process claim (i.e. a product-by-process within a product-by-process. Therefore as per *In re Brown*, 173 USPQ 685 (CCPA 1972); *In re Wertheim*, 191 USPQ (CCPA 1976), it is the product that has to be met and not the process steps in either claim. Therefore, it is being held that since the phospholipid of claim 107 has been rendered obvious, so too the phospholipid of claim 108.

Response to Arguments

Applicant's arguments filed 3/10/2011 have been fully considered but they are not persuasive.

Applicant states that Kyle does not disclose a vegetarian diet for the aquatic animal and the allowability of the claims should be based on such a fact. This was found to be unpersuasive as addressed in the rejection itself.

Next, applicant states that Barclay is inapplicable because Barclay discloses the use of biomass as a food additive and not as a replacement feed. This is also unpersuasive because the purpose of the ingredient is of no concern in a product claim. Applicant states that by disclosing the biomass as a food additive, the DHA level in the animal cannot be determined. This is found to be unconvincing as a reason for allowance because it is not credible that the DHA was not elevated by the feed and that it cannot be measured because the ingredient was a food additive. No reason has been given to substantiate this remark. Applicant further states that the references as applied in the previous action do not meet the newly amended claims. However, this is deemed moot in view of the new grounds of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Sayala, whose telephone number is (571) 272-1405. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. SAYALA/
Primary Examiner, Art Unit 1781